

IN THE CIRCUIT COURT OF THE SIXTH JUDICIAL CIRCUIT  
IN AND FOR PASCO COUNTY, STATE OF FLORIDA

ADALBERTO ACOSTA RIVERA,

Plaintiff,

vs.

Case No.: \_\_\_\_\_

Division: H

51-2007-CA 001818 WS

MERCK & CO., INC., PFIZER, INC.,  
PHARMACIA CORPORATION,  
a wholly-owned subsidiary of PFIZER, INC.,  
PHARMACIA & UPJOHN COMPANY, LLC,  
a wholly-owned subsidiary of PHARMACIA  
CORPORATION, G.D. SEARLE LLC (f/k/a  
G.D. SEARLE & CO.), and MONSANTO COMPANY

Defendants.

**COMPLAINT**

Plaintiff, ADALBERTO ACOSTA RIVERA, sues Defendants, MERCK & CO., INC., PFIZER, INC., PHARMACIA CORPORATION, a wholly-owned subsidiary of PFIZER, INC., PHARMACIA & UPJOHN COMPANY, LLC, a wholly-owned subsidiary of PHARMACIA CORPORATION, G.D. SEARLE LLC (f/k/a G.D. SEARLE & CO.), and MONSANTO COMPANY and alleges as follows:

**GENERAL ALLEGATIONS**

1. This is an action for damages in excess of \$15,000.00.
2. Plaintiff, ADALBERTO ACOSTA RIVERA, at all times material hereto, was a resident of Pasco County, Florida.
3. On May 28, 2004, Plaintiff ADALBERTO ACOSTA RIVERA, suffered a heart attack resulting in permanent damages and disability as a result of his ingestion of Vioxx, Celebrex and Bextra.

4. MERCK & CO., INC. (hereafter referred to as "MERCK") is a New Jersey Corporation with its principal place of business located in Whitehouse Station, New Jersey.

5. At all times material hereto, MERCK was authorized and did conduct business within the State of Florida.

6. PFIZER, INC. (hereafter referred to as "PFIZER") is a Delaware Corporation with its principal place of business at 235 E. 42nd Street, New York, NY.

7. At all times material hereto, PFIZER was authorized and did conduct business within the State of Florida.

8. PHARMACIA CORPORATION ("PHARMACIA") is a Delaware Corporation with its principal place of business in New Jersey.

9. At all times material hereto, PHARMACIA was a wholly-owned subsidiary of PFIZER.

10. PHARMACIA & UPJOHN COMPANY, LLC ("PHARMACIA & UPJOHN") is a Delaware Corporation with its principal place of business in New York.

11. At all times material hereto, PHARMACIA & UPJOHN, was a wholly-owned subsidiary of Defendant PHARMACIA.

12. At all times material hereto, PFIZER was responsible for the liabilities of PHARMACIA and PHARMACIA & UPJOHN.

13. G.D. SEARLE LLC ("SEARLE"), formerly known as G.D. SEARLE & Co., is a Delaware corporation with its principal place of business in Illinois. In April of 2000, SEARLE was acquired by PHARMACIA, and became a wholly-owned subsidiary of PHARMACIA. At the time of Pfizer's acquisition of PHARMACIA, SEARLE was a wholly-owned subsidiary of

PHARMACIA, acting as its agent and alter ego in all matters alleged in this Complaint, and is now a wholly-owned subsidiary of PFIZER.

14. MONSANTO COMPANY ("MONSANTO") was the parent corporation of SEARLE and is a Delaware corporation.

15. As used herein, Defendants PFIZER, PHARMACIA, and PHARMACIA & UPJOHN are collectively referred to as "BEXTRA DEFENDANTS".

16. At all times material, the BEXTRA DEFENDANTS were in the business of developing, manufacturing, selling, distributing, labeling, marketing and/or promoting Bextra for consumer use by prescription. The BEXTRA DEFENDANTS did develop, manufacture, design, package, market, sell and distribute Bextra in the State of Florida at all times relevant to this action.

17. As used herein, Defendants PFIZER, SEARLE, PHARMACIA, and MONSANTO are collectively referred to as "CELEBREX DEFENDANTS".

18. At all times material, the CELEBREX DEFENDANTS were in the business of developing, manufacturing, selling, distributing, labeling, marketing and/or promoting Celebrex for consumer use by prescription. The CELEBREX DEFENDANTS did develop, manufacture, design, package, market, sell and distribute Celebrex in the State of Florida at all times relevant to this action.

19. Vioxx, Celebrex, and Bextra are among a class of pain medication called non-steroidal anti-inflammatory drugs "NSAIDs"). Aspirin, naproxen (trade name Aleve), and ibuprofen (trade name Advil) are examples of well-known NSAIDs.

20. NSAIDs reduce pain and inflammation by blocking the body's production of pain transmission enzymes called cyclooxygenase (COX-1 and COX-2). COX enzymes trigger the

sequential oxidation of various fatty acids to create prostaglandins. Prostaglandins are important cogs in the physiology of pain, igniting hormone-like actions in the immediate vicinity of the cells that release them, thereby inducing inflammation, pain, and fever.

21. Because COX enzymes and prostaglandins increase the pain associated with tissue injury, the synthesis of prostaglandins by cells of injured tissue becomes a reasonable target for pain-management drugs.

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22. Traditional NSAIDs like aspirin, ibuprofen, and naproxen inhibit both COX-1 and COX-2 enzymes simultaneously, providing relief from the inflammation and pain, but at the cost of potential adverse gastrointestinal effects. The prostaglandins that are supported by COX-1 enzymes are involved in the production of gastric mucus which protects the stomach wall from the hydrochloric acid present in the stomach. By blocking the COX-1 enzyme, the body's ability to protect gastric tissue is hampered and, as a result, can cause harmful gastrointestinal side effects, including stomach ulcerations and bleeding.

23. MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS, and other pharmaceutical companies sought to remedy these side effects suffered by some NSAID users by developing "selective" inhibitors, called coxibs, which targeted only COX-2 production; thus (allegedly) allowing for proper maintenance of gastric tissue while still reducing inflammation. Their development was based on the hypothesis that COX-2 was the source of prostaglandins E2 and I2, which mediate inflammation, and that COX-1 was the source of the same prostaglandins in the stomach lining. By not inhibiting COX-1, whose products provide cytoprotection in the gastric epithelium, these coxibs were thought to decrease the incidence of gastric side effects when compared to traditional NSAIDs that inhibit both COX-1 and COX-2.

24. In making this decision, however, MERCK, the CELEBREX DEFENDANTS,

and the BEXTRA DEFENDANTS either intentionally ignored and/or recklessly disregarded current medical knowledge that selective COX-2 inhibition lowers prostaglandin I2 levels, the predominant COX-2 product responsible for preventing platelet aggregation and clotting, while leaving thromboxane A2, the potent COX-1 platelet aggregator and vasoconstrictor, unaffected. By selectively inhibiting prostaglandin I2 without similarly suppressing its COX-1 counterpart, Vioxx and other coxibs expose their users to a host of blood clot-related cardiovascular risks, including heart attack, stroke, and unstable angina.

**A. Factual Background Relating To Defendant,  
MERCK & CO., INC. ("MERCK") and Vioxx**

25. This action arises out of MERCK's manufacturing, selling, distributing, marketing and/or otherwise promoting Vioxx in the State of Florida without proper warnings as to the dangers associated with its use.

26. The pharmaceutical drug Vioxx, manufactured by MERCK & CO., INC., is defective, dangerous to human health, and unfit and unsuitable to be marketed and sold in commerce.

27. At all times material, MERCK was in the business of developing, manufacturing, selling, distributing, labeling, marketing and/or promoting Vioxx (rofecoxib) for consumer use by prescription. MERCK did develop, manufacture, design, package, market, sell and distribute Vioxx in the State of Florida at all times relevant to this action, but withdrew Vioxx from the market on September 29, 2004.

28. In the late 1980s and early 1990s, MERCK was facing a business crisis because patents on several of its best-selling drugs, including Vasotec, Prinivil, Mevacor, Pepcid, and Prilosec were expiring. Never had a pharmaceutical company faced the loss of so many million

dollar patents at the same time. MERCK management even feared that MERCK might not survive as a company.

29. In or about the summer of 1992, MERCK began a Cox-2 research program at the MERCK Frosst Centre for Therapeutic Research in Quebec, Canada. MERCK scientists explored the hypothesis that the therapeutic utilities of NSAIDs were due to inhibition of Cox-2, whereas much of the gastrointestinal toxicity of traditional NSAIDs were due to the inhibition of Cox-1.

30. At the time, MERCK management realized that the development of an NSAID that operated by selectively blocking Cox-2 could produce a much-needed "blockbuster" for the company. As the company has acknowledged, the race was on to find a selective inhibitor of Cox-2.

31. During 1992, MERCK became aware that both DuPont and Taisho, a Japanese pharmaceutical company, had selective Cox-2 inhibitors in development. Almost every one of the more than three hundred scientists and support staff at MERCK-Frosst Centre for Therapeutic Research worked on the discovery and development of Vioxx. After discarding one compound because it lacked sufficient selectivity for Cox-2, and another because metabolic studies raised questions of possible drug-to-drug interactions, MERCK continued to research and develop the compound that eventually became known as Vioxx.

32. On or about December 20, 1994, MERCK filed its first investigational new drug (IND) application with the FDA to conduct clinical trials of Vioxx on humans. The intended use of the drug identified in the IND was the treatment of osteoarthritis and acute pain.

33. MERCK sought to market Vioxx as an alternative to earlier NSAIDs such as aspirin, which had frequently been associated with adverse gastrointestinal side effects. As early

as November 1996, years before FDA approval of Vioxx in May of 1999, MERCK recognized that unless taken in conjunction with aspirin, Vioxx posed a “substantial risk” of “significantly higher rates” of cardiovascular adverse events such as myocardial infarctions, strokes and transient ischemic attacks because, as a selective Cox-2 inhibitor, it lacked aspirin’s “anti-platelet [i.e. anti-clotting] effect”.

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34. In fact, early in the development program for Vioxx, to demonstrate that it selectively inhibited Cox-2, MERCK used a platelet aggregation assay to assess the drug’s effect on Cox-1. That research established that Vioxx did not affect thromboxane production or platelet aggregation because it did not inhibit Cox-1. In addition, a MERCK-sponsored study found that Vioxx, unlike several other NSAIDs against which it was tested, had no appreciable anti-platelet effect (Protocol 061).

35. Two months later, in February of 1997, Vioxx researcher Briggs Morrison conceded that “without Cox-1 inhibition you will get more thrombotic events and kill drug.”

36. Responding to this observation, on February 25, 1997, MERCK’s Vice President of Clinical Research, Alise Reicin, complained:

I hear you! This is a no win situation. The relative risk of [adverse GI events with] even low dose aspirin is 2-4 fold. Yet, the possibility of increased CV [cardiovascular] events of great concern-(I just can’t wait to be the one to present those results to senior management!). What about the idea of excluding high risk CV patients – ie (sic) those that have already had an MI, CABG, PTCA.? This may decrease the CV event rate so that a difference between the two groups would not be evident. The only problem would be would we be able to recruit any patients?

37. In December of 1997, MERCK appointed a “Task Force” to investigate the incidence of cardiovascular serious adverse events in the ongoing Vioxx clinical trials. The reason for the investigation was the unexpected results of an early clinical trial which showed a

decline in the levels of PGI-2, the most potent of all inhibitors of platelet aggregation, but no inhibition of systemic thromboxane, in the urinalysis of patients on Vioxx. This imbalance triggered a concern over the potential for thrombotic events.

38. By early 1998, MERCK's own clinical investigators, [based on findings from a MERCK-sponsored study (protocol 023)] advised the company that by inhibiting Cox-2, Vioxx, at the cellular level of blood vessel linings, may alter the homeostatic balance between prostacyclin (a Cox-2 platelet inhibitor that dilates blood vessels) and thromboxane (a Cox-1 platelet activator that constricts blood vessels) such that it would provoke the creation of blood clots.

39. The Task Force agreed to investigate the incidence of thrombotic events by analyzing the ongoing osteoarthritis (OA) trials. Because the trials were still blinded as to treatment groups, it could not be determined whether the adverse events in the database had occurred in the Vioxx, placebo or "compared to" drug populations. Therefore, the Task Force designed a study in which cardiovascular events from all arms of the OA trials would be added together, and the combined group's incidence rate would be compared to placebo patients from trials of other MERCK drugs. An expedited time frame was established for completion of the analysis, in light of the rush to get Vioxx to market ahead of its competitors.

40. In January of 1998, the analysis pursuant to the Task Force plan showed a statistically significant increased relative risk of 2.16 for females in the Vioxx study versus the placebo group selected by MERCK for comparison. These results constituted a clear signal of cardiovascular toxicity that should have triggered immediate investigation and concern. Instead, MERCK made an after-the-fact claim that the placebo comparison group must have had an "atypically low" incidence of cardiovascular events, such that the higher rate in the Vioxx group

was downplayed. MERCK further downplayed this important safety signal by deciding to compare the rate in the Vioxx group to a so-called “background” rate, even though no such comparison was stated in the plan for the study. MERCK intentionally chose an inappropriate “background” rate for comparison, from a published study of older patients at high risk of cardiovascular disease. Based upon the result of this comparison, MERCK incorrectly dismissed the signal as of no concern. MERCK failed to disclose the results of this pre-marketing analysis, and instead has misrepresented that it had no indication of cardiovascular risks before Vioxx was marketed.

41. MERCK submitted an Application to Market a New Drug for Human Use (“NDA”) for rofecoxib to the United States Food and Drug Administration (“FDA”) on November 23, 1998, for tablets at doses of 12.5 mg and 25 mg, for relief of the signs and symptoms of osteoarthritis, the management of acute pain, and the treatment of dysmenorrhea. This application was denoted NDA 21-042 by the FDA.

42. MERCK also submitted a NDA for rofecoxib to the FDA on November 23, 1998, for oral suspension at doses of 12.5 mg/mL and 25 mg/mL, for relief of the signs and symptoms of osteoarthritis, the management of acute pain, and the treatment of primary dysmenorrhea. This application was denoted as NDA 21-052 by the FDA.

43. On or about May 20, 1999, the FDA approved NDA 21-042 and NDA 21-052 (hereinafter the “NDA”) for rofecoxib, for the relief of the signs and symptoms of osteoarthritis, the management of acute pain, and the treatment of primary dysmenorrhea.

44. At the time that Vioxx was approved by the FDA, the labeling for rofecoxib (in the section entitled “Special Studies- Upper Endoscopy in Patients with Osteoarthritis”) stated “Treatment with VIOXX 25 mg daily or 50 mg daily was associated with a significantly lower

percentage of patients with endoscopic gastroduodenal ulcers than treatment with ibuprofen 2400 mg daily. However, the studies cannot rule out at least some increase in the rate of endoscopic gastroduodenal ulcers when comparing VIOXX to placebo.”

45. The “Warnings” section of the labeling for rofecoxib at the time the drug was approved by the FDA, contains a section, “Gastrointestinal (GI) effects—Risk of GI Ulceration, Bleeding and Perforation.”

46. MERCK submitted a Supplemental New Drug Application (“sNDA”) with the goal of establishing a gastrointestinal safety claim for rofecoxib. In conjunction with the sNDA, MERCK conducted a study known as the VIGOR (VIOXX GI Outcomes Research) Protocol, No. 088-04, entitled “A Double-Blind, Randomized, Stratified, Parallel-Group Study to Assess the Incidence of PUBs During Chronic Treatment With MK-09 or Naproxen in Patients With Rheumatoid Arthritis: U.S. Cohort.” The VIGOR study was conducted from January 6, 1999, through March 17, 2000.

47. The objectives of the VIGOR study were to “determine the relative risk of confirmed PUB (Perforation, Ulcers, Bleeding) in patients taking Vioxx 50mg daily compared to patients in the group taking naproxen 1000 mg/day” and to “study the safety and tolerability” of Vioxx in patients with rheumatoid arthritis.

48. The VIGOR study demonstrated that Vioxx is associated with a lower incidence of serious upper gastrointestinal adverse events of major bleeding, perforation, and obstruction compared to naproxen.

49. However, the VIGOR study also showed a higher cumulative rate of serious cardiovascular thromboembolic adverse events (such as heart attacks, angina pectoris, and peripheral vascular events) in the Vioxx group compared to the naproxen group.

50. On or about November 19, 1999, MERCK's senior biostatistician, Deborah Shapiro, provided a tightly controlled, highly confidential interim safety report to the VIGOR study's Data Safety and Monitoring Board ("DSMB"), which showed that almost twice as many serious cardiovascular events were occurring among patients taking Vioxx as among those taking Naproxen.

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51. On or about March of 2000, MERCK released the results of the VIGOR study. The study data revealed, among other things, that Vioxx users suffered five times as many heart attacks than their Naproxen counterparts. In addition, serious cardiovascular events (including ischemic strokes, unstable angina, and sudden unexplained deaths) were reported for more than twice as many Vioxx as Naproxen patients.

52. Despite the results of the VIGOR study, MERCK failed to include in its Vioxx label a cardiovascular warning that Vioxx was contraindicated in high risk CV patients or to warn physicians of this enhanced risk.

53. An FDA report, written by Shari L. Targum, M.D., a Project Manager for the FDA's Division of Anti-Inflammatory Drug Products, dated February 1, 2000, states: "By November 18, 1999, the Data and Safety Monitoring Board of the VIGOR study, a committee independent from MERCK, the sponsor, had become concerned over the "excess deaths and cardiovascular events experienced in Group A [Vioxx] compared to Group B [naproxen]."

54. On March 9, 2000, shortly after completion of the VIGOR study, Edward M. Scolnick, former president of MERCK Research Laboratories, concluded that "the CV [cardiovascular] events are clearly there" and stated that MERCK should be prepared to "make clear to the world" that Vioxx's cardiovascular toxicity "is a class effect" (i.e. an effect of all of

the selective Cox-2 inhibitors and not a risk that was associated only with Vioxx) that is “mechanism based as we worried it was” and as some of the company’s consultants had maintained.

55. MERCK continued to publish and describe that Naproxen had a cardioprotective effect, notwithstanding that Italian pharmacologist Carlo Patrono, one of MERCK’s own consultants and an expert in the platelet effects of cyclooxygenase-inhibiting drugs (whom MERCK regarded as “the world’s most respected and knowledgeable” scientist in his field), advised MERCK in March of 2000 that the dramatic cardiovascular effects observed in the VIGOR study could not plausibly be attributed to Naproxen for several reasons.

56. Furthermore, on or about March 24, 2000, University of Pennsylvania pharmacologist Garrett Fitzgerald, then acting as a MERCK consultant, advised MERCK of a scientific paper about to be published that included Naproxen among several NSAIDs which, in contrast to aspirin, had no significant effect on the incidence of first nonfatal myocardial infarctions in females in an epidemiological study, providing further notice to MERCK that its insistence that Naprosen was cardioprotective was a fallacy.

57. In June of 2000, in connection with industry-sponsored studies presented at the European United League Against Rheumatism (EULAR), an organization in which MERCK is a member and corporate sponsor, it was shown that Vioxx use resulted in a statistically significant increase in hypertension and stroke. Not only did MERCK do nothing to accurately publish these studies, or warn consumers and prescribing doctors, MERCK also denied the results with respect to hypertension in the official publication of the American Pharmaceutical Association, *Pharmacy Today*, *Spin War Aside, Lessons Emerge from COX-2 Trials*, in August of 2000.

58. MERCK concealed the serious cardiovascular risks associated with Vioxx because a successful launch of Vioxx was viewed as critical for the success of MERCK as a company. Safety concerns over hypertension, thrombosis, edema, and/or cardiovascular events would have negatively impacted MERCK's positioning in the market as compared to its competitor drug, Bextra (celecoxib), which had been placed into the market by Pharmacia and Pfizer three months prior to the launch of Vioxx.

59. MERCK continued to deny the ill health effects associated with Vioxx while at the same time reaping benefits obtained through its non-disclosure and concealment. MERCK engaged in a massive physician and direct-to-consumer advertising and sampling program and gained continued increases in the market share, which enhanced MERCK's financial stability to the detriment of its consumers. As a result of MERCK's scheme, it reaped more than \$2 billion in profit in the year 2000 alone, and garnered approximately a 23% share of the market.

60. The FDA sent a letter to MERCK dated December 16, 1999, stating that certain Vioxx promotional pieces "are false and misleading because they contain representations of Vioxx's safety profile, unsubstantiated comparative claims, and are lacking in fair balance."

61. On June 22, 1999, MERCK contracted with Peter Holt, M.D., to conduct Vioxx promotional audio conferences, using content provided by MERCK, which were to be presented to health care professionals as educational programs. The conferences (one on June 8, 2000; one on June 13, 2000; one on June 16, 2000, and three on June 21, 2000) were arranged by MERCK, presented on behalf of MERCK, and moderated by MERCK employees. Some of the content of these conferences was later found by the FDA to be "false or misleading in that they minimized the MI results of the VIGOR study, minimized the Vioxx/Coumadin drug interaction, omitted

important risk information, made unsubstantiated superiority claims, and promoted Vioxx for unapproved uses and an unapproved dosing regimen.”

62. Further, in its January 23, 2001, 8-K filing with the Securities and Exchange Commission, MERCK fails to mention the cardiac and cardiothrombotic findings of the VIGOR study:

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Our results reflect the strength of our growth strategy," Mr. Gilmartin said. "Our five key products, Vioxx, Zocor, Cozaar/Hyzaar, Fosamax, and Singular, drove MERCK's performance for the year and created a powerful platform for growth." These products accounted for 57% of MERCK's worldwide human health sales for 2000 and 61% for the fourth quarter.

Each of the five medicines offers unique competitive advantages," Mr. Gilmartin said. Vioxx, a once-a-day medicine, is the only COX-2 indicated in the United States both for osteoarthritis and acute pain. Since its extraordinary successful 1999 launch, Vioxx has become the world's fastest growing branded prescription arthritis medicine, and it is already MERCK's second largest-selling medicine. In the United States, Vioxx now accounts for approximately 50% of the new prescriptions in the COX-2 class, despite being second to market in this class in the United States. Vioxx achieved \$2.2 billion in sales for the full year 2000, with \$700 million in the fourth quarter.

A Food and Drug Administration (FDA) Advisory Committee meeting is scheduled for Feb. 8 to review labeling changes MERCK has requested based on the strong results of the VIGOR study, in which Vioxx reduced the risk of serious gastrointestinal outcomes research study, in which Vioxx reduced the risk of serious gastrointestinal complications by half compared to the NSAID naproxen, was published in November in THE NEW ENGLAND JOURNAL OF MEDICINE. Another study, presented in November, showed that Vioxx significantly reduced moderate-to-severe acute pain after dental surgery to a greater degree compared to codeine combined with acetaminophen.

63. In response to the growing public expressions of concern over the cardiovascular safety profile of Vioxx, MERCK issued a press release entitled "MERCK Confirms Favorable Cardiovascular Safety Profile of Vioxx," dated May 22, 2001. This press release states that Vioxx has a "favorable cardiovascular safety profile." The FDA would later tell MERCK:

Your claim in the press release that Vioxx has a "favorable cardiovascular profile" is simply incomprehensible, given the rate of MI [myocardial infarction] and serious cardiovascular events compared to naproxen. The implication that Vioxx's cardiovascular profile is superior to other NSAIDs is

misleading; in fact, serious cardiovascular events were twice as frequent in the Vioxx treatment group...as in the naproxen treatment group... in the VIGOR study.

64. Despite admonishments from the FDA for its fraudulent marketing, MERCK continued to increase sales of Vioxx and profits by withholding information from Plaintiff, prescribing doctors, the consuming public, and the health care industry. For example, in November of 2000, MERCK orchestrated the publication of a study in the New England Journal of Medicine in which it knowingly downplayed and/or withheld the severity of cardiovascular risks associated with Vioxx consumption over naproxen consumption.

65. On or about August 29, 2001, the Journal of American Medical Association (JAMA) published a peer reviewed epidemiologic study by the Cleveland Clinic Foundation, Cleveland, Ohio, showing that MERCK had concealed the risk of developing a “confirmed adjudicated thrombotic cardiovascular event” (defined in the article as “myocardial infarction, unstable angina, cardiac thrombus, resuscitated cardiac arrest, sudden or unexplained death, ischemic stroke, and transient ischemic attacks”) among Vioxx users in MERCK’s clinical trials, including VIGOR. The study found a statistically increased risk (of the magnitude of a four to five-fold increase) for developing serious cardiovascular events, including heart attacks, in Vioxx users over placebo and naproxen.

66. In the JAMA study, the authors stated that “by decreasing PG12 production [Vioxx] may tip the natural balance between prothrombotic thromboxane A2 and antithrombotic PG12, potentially leading to an increase in thrombotic cardiovascular events.”

67. On September 17, 2001, Thomas W. Abrams, R. Ph., MBA, Director of the FDA Division of Drug Marketing, Advertising, and Communications, issued a “Warning Letter” to

Raymond V. Gilmartin, President and CEO of MERCK, relating to “promotional activities and materials for the marketing of Vioxx (refecoxib) tablets.”

68. The Warning Letter, MERCK’s third such letter from the FDA concerning Vioxx, stated that MERCK had “engaged in a promotional campaign for Vioxx that minimizes the potentially serious cardiovascular findings that were observed in the Vioxx Gastrointestinal Outcomes Research (VIGOR) study, and thus, misrepresents the safety profile for Vioxx.” The letter further states:

Specifically, your promotional campaign discounts the fact that in the VIGOR study, patients on Vioxx were observed to have a four to five fold increase in myocardial infarctions (MIs) compared to patients on the comparator non-steroidal anti-inflammatory drug (NSAID), Naprosyn (naproxen).

69. The eight-page Warning Letter outlines, in detail, the conduct of MERCK that supports the FDA’s issuance of the Warning Letter, and makes the following “Conclusions and Requested Actions”:

The promotional activities and materials described above minimize the potentially serious cardiovascular findings that were observed in the VIGOR study, minimize the Vioxx/Coumadin drug interaction, omit crucial risk information associated with Vioxx therapy, contain unsubstantiated comparative claims, and promote unapproved uses. On December 16, 1999, we also objected to your dissemination of promotional materials for Vioxx that misrepresented Vioxx’s safety profile, contained unsubstantiated comparative claims, and lacked fair balance.

Due to the seriousness of these violations, and the fact that your violative promotion of Vioxx has continued despite our prior written notification regarding similar violations, we request that you provide a detailed response to the issues raised in this Warning Letter on or before October 1, 2001.

This response should contain an action plan that includes a comprehensive plan to disseminate corrective messages about the issues discussed in this letter to the audiences that received these misleading messages. This corrective action plan should also include:

Immediately ceasing all violative promotional activities, and the dissemination of all violative promotional materials for Vioxx.

Issuing a "Dear Healthcare Provider" letter to correct false or misleading impressions and information. The proposed letter should be submitted to us for review prior to its release. After agreement is reached on the content and audience, the letter should be disseminated by direct mail to all healthcare providers who were, or may have been exposed to the violative promotion.

70. MERCK knew the warnings contained in the label were ineffective and used its sales force and other marketing efforts to downplay (rather than improve) its communication of the risks posed by Vioxx. For example, in its 2001 annual report, MERCK states: "The Company also noted that a number of state and federal lawsuits, involving individual claims as well as purported class actions, have been filed against the Company with respect to Vioxx....these lawsuits include allegations regarding gastrointestinal bleeding and cardiovascular events. The Company believes that these lawsuits are without merit and will vigorously defend them." Sales representatives were instructed not to discuss cardiovascular risks of Vioxx and were trained to "dodge" physicians' Vioxx-related safety concerns.

71. In response to a growing body of evidence of Vioxx's safety problems, MERCK attempted to obfuscate this negative information by authoring and sponsoring reviews that set forth the unsubstantiated claim that naproxen had a cardioprotective effect and therefore accounted for the cardiovascular risks among its Vioxx users. However, this theory was debunked in January of 2002, by a Vanderbilt University School of Medicine human epidemiologic peer-reviewed study published in *The Lancet*. The *Lancet* article concluded that there is an absence of a protective effect of naproxen or other non-aspirin, non-steroidal anti-inflammatory drugs on the risk of coronary heart disease.

72. An article entitled "Why Do Cyclooxygenase-2 Inhibitors Cause Cardiovascular Events?" authored by Dr. Bing, Dr. Lomnicka, and others at the Department of Experimental Cardiology at the Huntington Medical Research Institute was published in the journal

*Pharmacology* on February 6, 2002. The authors explained that a selective Cox-2 inhibitor, such as Vioxx, can promote adverse cardiovascular events by tipping the balance of prostacyclin and thromboxane in favor of thromboxane. This imbalance promotes both platelet aggregation and vasoconstriction, which can lead to catastrophic cardiovascular events, including stroke, heart attack, and pulmonary embolism.

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73. In October of 2001, MERCK learned of the publication of an article stating that there was a higher reporting rate for adverse events relating to renal and cardiovascular effects for Vioxx compared to Bextra,. MERCK responded by conducting an internal analysis of reported adverse events for Vioxx and Bextra. MERCK's analysis showed a greater reporting rate of myocardial infarction, as well as congestive heart failure and related illnesses, for Vioxx in comparison to Bextra. Once again, MERCK disregarded yet another signal of cardiovascular toxicity and failed to disclose it to the public. Instead, MERCK blamed the adverse result on an alleged discrepancy in the number of events entered into the regulatory database for the two drugs. As was the case with the Task Force analysis of 1997 and VIGOR study of 2000, MERCK once again searched for and found a reason to exonerate Vioxx and keep it on the market rather than provide accurate information about safety risks to physicians and patients.

74. In approximately April of 2002, MERCK was required to place cardiovascular warnings on its Vioxx labeling based on the results of the VIGOR study. In addition, MERCK was required to place new label warnings relaying that Vioxx 50 mg per day is not recommended for chronic use.

75. An article by Dr. Solomon and others at Harvard Medical School, entitled "Relationship between Selective Cyclooxygenase-2 Inhibitors and Acute Myocardial Infarction in Older Adults," was published in the April 2004 edition of the journal *Circulation*. The

Harvard authors concluded the following from their study: “[R]ofecoxib [Vioxx] use was associated with an elevated relative risk of AMI [acute myocardial infarction] compared with celecoxib [Bextra] use and no NSAID use. Dosages of rofecoxib [greater than] 25 mg were associated with a higher risk than dosages [less than or equal to] 25 mg.”

76. An article by H.K. Choi in the May 2004 edition of the *American Journal of Medicine*, entitled “Effects of Rofecoxib and Naproxen on Life Expectancy Among Patients with Rheumatoid Arthritis: A Decision Analysis,” concludes the following: “Our analysis suggests a longer life expectancy with naproxen than rofecoxib [Vioxx] ....except those at low risk for myocardial infarction or at a high risk for gastrointestinal toxicity.”

77. David Graham, M.D., an employee of the Food & Drug Administration, made a poster presentation entitled “Risk of Acute Myocardial Infarction and Sudden Cardiac Death with Use of COX-2 Selective and Non-Selective NSAIDs” at the 20<sup>th</sup> International Conference on Pharmacoepidemiology and Therapeutic Risk Management, held from August 22-25, 2004, in Bordeaux, France. The data for the presentation was taken from a study done by Kaiser Permanente under a contract funded by the FDA, and concluded that Vioxx taken at more than 25 mg per day increased the risk of heart attack and sudden cardiac death by 300% in those enrolled in the Kaiser Permanente study.

78. On August 26, 2004, Peter Kim, President of MERCK Research Laboratories, issued a press release stating the following: “MERCK strongly disagrees with the conclusions of an observational analysis by Graham, et al., presented at an international meeting this week . . . . MERCK stands behind the efficacy and safety, including cardiovascular safety of Vioxx.”

79. On September 27, 2004, MERCK informed the FDA that the Data Safety Monitoring Board for an ongoing long-term study of Vioxx, known as the APPROVe study, had recommended that the study be stopped early for safety reasons.

80. The APPROVe study was not intended to be a cardiovascular risk assessment study. It was commissioned by MERCK to look at the effect of Vioxx on people at risk for developing recurrent colon polyps.

81. The APPROVe study demonstrated an increased risk of cardiovascular adverse events, including heart attacks and strokes, for the Vioxx population relative to the placebo population in the study. Defendant Merck has falsely claimed that the APPROVe data only showed an increased risk for people taking Vioxx for more than 18 months. Merck's claim has since been discredited.

82. MERCK representatives informed the FDA in a September 28, 2004, meeting that MERCK would withdraw Vioxx from the United States market.

83. MERCK and the FDA each announced the withdrawal of Vioxx from the United States market on September 30, 2004. MERCK also announced worldwide withdrawal on the same day.

84. An FDA analysis, based on data from the Kaiser Permanente study, projects that 27,785 heart attacks and sudden cardiac deaths "would have been avoided" had Bextra, another Cox II inhibitor, been used instead of Vioxx.

85. Approximately 20 million people in the United States took Vioxx between its introduction in 1999 and its withdrawal in 2004, and, during this time period, MERCK engaged in a common scheme in marketing, distributing and/or selling Vioxx under the guise that it was safe and efficacious for persons such as Plaintiff.

86. At all times relevant to this litigation, MERCK enjoyed a significant market share based upon false claims of Vioxx's efficacy, safety, and superiority which resulted a result of the actions of Defendants, including a very aggressive marketing program which included financial incentives to sales teams, the hiring of 700 new sales representatives, significant payments and other benefits to high-prescribing physicians, and a massive direct-to-consumer advertising and physician sampling program. MERCK encouraged the prescription and use of Vioxx through aggressive marketing campaigns, including detailing of physicians by Defendants and others as well as direct-to-consumer advertising. As such, Defendants had a duty not only to provide Plaintiff's prescribing physician with adequate warnings but also to provide Plaintiff with adequate warnings regarding Vioxx and the safety risks associated with ingestion of the drug.

87. In an elaborate and sophisticated manner, MERCK aggressively marketed Vioxx directly to consumers and medical professionals (including physicians and leading medical scholars) in order to leverage pressure on third party payors, medical care organizations, and large institutional buyers (*e.g.*, hospitals) to include Vioxx on their formularies. Faced with the increased demand for the drug by consumers and health care professionals that resulted from MERCK's successful advertising and marketing blitz, third party payors were compelled to add Vioxx to their formularies. MERCK's marketing campaign specifically targeted third party payors, physicians, and consumers, and was designed to convince them of both the therapeutic and economic value of Vioxx.

88. MERCK knew of the cardiovascular risks before the U.S. Food and Drug Administration (the "FDA") approved Vioxx for sale, but they ignored, downplayed, suppressed, omitted, and concealed these serious safety risks and denied inefficacy in its promotion, advertising, marketing, and sale of Vioxx. MERCK's omission, suppression, and concealment

of this important information enabled Vioxx to be sold to, and purchased, or paid for by the consumers at a grossly inflated price.

89. Because MERCK engaged in a promotional and marketing campaign that featured an advertising blitz directly targeted to consumers, that touted Vioxx as a safer drug than other drugs in its class, while uniformly failing to disclose the health risks of Vioxx, MERCK was able to justify pricing Vioxx significantly higher than the cost of generic aspirin. In reality, that price inflation was not justified. Had MERCK disclosed the truth about Vioxx, MERCK would not and could not have reaped the billions of dollars in Vioxx sales that were achieved as a direct result of the concealment, omission, suppression, and obfuscation of the truth.

90. MERCK intentionally, deliberately, knowingly, and actively concealed, omitted, suppressed, and obfuscated important and material information regarding the risks, dangers, defects, and disadvantages of Vioxx from Plaintiff, the public, the medical community, and others. This concealment and omission was deliberate, knowing, active, and uniform, was intended to induce and maximize sales and purchases of Vioxx, and prevented Plaintiff from obtaining all the material information that would be important to his decision as a reasonable person to purchase, pay for, and/or use Vioxx.

91. MERCK's systematic, active, knowing, deliberate, and uniform concealment, omissions, suppression, and conduct caused Plaintiff to purchase, pay for, and/or use Vioxx; and caused Plaintiff's losses and damages as asserted herein.

92. Had MERCK performed adequate testing prior to approval and "market launch," the scientific data would have revealed significant increases in stroke and myocardial infarctions amongst the intended population of Vioxx consumers. Adequate testing would have shown that Vioxx possessed serious side effects. MERCK should have taken appropriate measures to ensure

that their defectively designed product would not be placed into the stream of commerce and/or should have provided full and proper warnings that accurately and fully reflected the scope and severity of adverse effects associated with Vioxx.

93. In fact, post-market approval data did reveal increased risks of clotting, stroke and myocardial infarction, but MERCK intentionally suppressed this information in order for them to gain significant profits from continued Vioxx sales.

94. MERCK's failure to conduct adequate testing and/or additional testing prior to "market launch" was based upon their desire to generate maximum financial gains for MERCK and to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

95. At the time that MERCK manufactured, advertised and distributed VIOXX to consumers including Plaintiff, MERCK intentionally or recklessly ignored and/or withheld information regarding the increased risks of hypertension, stroke and/or myocardial infarctions because MERCK knew that if such increased risks were adequately disclosed, consumers would not purchase Vioxx, but instead would purchase other cheaper and safer NSAID drugs.

96. Defendants misrepresented the safety and effectiveness of Vioxx to prescribing physicians, Plaintiff, scientific journals, and the consuming public, and concealed or understated the dangerous side effects associated with ingestion of Vioxx. Defendants also engaged in such aggressive, improper, and dishonest promotion to certain physicians that the prescribing physicians were no longer able to make independent decisions as a learned intermediary on behalf of their patients.

97. As a direct and legal result of the defective condition of the Vioxx manufactured and marketed by Defendants and ingested by Plaintiff, Plaintiff has suffered and continues to

suffer from serious injuries, including, but not limited to, pain and suffering, physical injuries, disability, disfigurement, embarrassment, mental anguish, loss of capacity for the enjoyment of life, expenses of hospitalization, medical, nursing care and treatment, loss of earnings, loss of the ability to earn money in the future, and a shortened life span.

**B. Factual Background Relating To BEXTRA DEFENDANTS**

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98. This action arises out of the BEXTRA DEFENDANTS' manufacturing, selling, distributing, marketing and/or otherwise promoting Bextra in the State of Florida without proper warnings as to the dangers associated with its use.

99. The pharmaceutical drug Bextra, manufactured by the BEXTRA DEFENDANTS, is defective, dangerous to human health, and unfit and unsuitable to be marketed and sold in commerce.

100. Bextra (generic name valdecoxib) is a Cox-2 selective non-steroidal anti-inflammatory drug (NSAID).

101. Bextra is used in the treatment of arthritis and is among the class of drugs known as NSAIDs, which are non-steroidal anti-inflammatory drugs including aspirin, naproxen (trade name Aleve), and ibuprofen (trade name Advil).

102. NSAIDs reduce pain and inflammation by blocking the body's production of pain transmission enzymes called cyclooxygenase (Cox-1 and Cox-2). Cox enzymes trigger the sequential oxidation of various fatty acids to create prostaglandins. Prostaglandins are important cogs in the physiology of pain, igniting hormone-like actions in the immediate vicinity of the cells that release them, thereby inducing inflammation, pain, and fever.

103. Because Cox enzymes and prostaglandins increase the pain associated with tissue injury, the synthesis of prostaglandins by cells of injured tissue becomes a reasonable target for

pain-management drugs.

104. At the time the BEXTRA DEFENDANTS developed and manufactured Bextra, the BEXTRA DEFENDANTS intended to capture a portion of the extremely lucrative consumer market for Cox-2 specific inhibitors.

105. Bextra was approved on November 19, 2001, for marketing in the United States. Bextra was a second-generation Cox-2 inhibitor from PFIZER, which also manufactures Celebrex (celexoxib). Bextra, a stronger Cox-2 inhibitor than Celebrex, was approved for use in patients with osteoarthritis and adult rheumatoid arthritis. Bextra is a selective Cox-2 inhibitor with similar selectiveness to Vioxx, a drug manufactured by Merck.

106. The scientific data available during and after Bextra's approval should have alerted the BEXTRA DEFENDANTS that its formulation of Bextra could cause a higher risk of clotting, stroke and/or myocardial infarctions among Bextra users. In addition, the scientific data available should have also alerted the BEXTRA DEFENDANTS that Bextra users faced special risks of potentially fatal skin and systemic reactions that were unique to Bextra.

107. Based upon the scientific data available in its own studies, the BEXTRA DEFENDANTS knew or in the exercise of reasonable care should have known that additional testing should be performed to determine the adverse health effects of Bextra on intended consumers.

108. In approximately June of 2003, the BEXTRA DEFENDANTS completed a study that showed an excess risk of cardiovascular events for persons ingesting Bextra. As reported in the Wall Street Journal, "*PFIZER to Begin Test of Celebrex as Heart Attack Inhibitor; Questions Raised on Timing, C-5*," the BEXTRA DEFENDANTS had possession of the adverse cardiovascular data from a second study at least by August of 2004, but failed to make any

disclosure until after October 15, 2004. The BEXTRA DEFENDANTS referred to the adverse cardiovascular thrombotic events at issue as an "open question" since the studies were on non-indicated uses, and the BEXTRA DEFENDANTS had not done the necessary long-term, prospective, randomized placebo controlled clinical trials to further quantify the risk.

109. The BEXTRA DEFENDANTS were also aware of a study published by Dr. Eric Topol in August of 2001 in the *Journal of the American Medical Association* that reported an increased risk of thrombotic cardiovascular events in persons who used Cox-2 inhibitors. The study theorized that Cox-2 inhibitors interfered with platelet aggregation and had the potential to cause clot formation. Dr. Garrett Fitzgerald, of the University of Pennsylvania, in an editorial published in the *New England Journal of Medicine* on October 21, 2004, reported that it was known as early as 1999 that the Cox-2 inhibitors suppressed the formation of prostaglandin I<sub>2</sub> in healthy volunteers, that this action inhibited platelet aggregation *in vitro*, and that this may predispose patients to myocardial infarction or thrombotic stroke.

110. Based upon available scientific data, the BEXTRA DEFENDANTS knew or should have known that the study group involved in its own testing did not adequately represent the cross-section of individuals who were the intended consumers likely to take Bextra. Therefore, the testing performed was inadequate.

111. At all times up until Plaintiff was injured, the BEXTRA DEFENDANTS did not carry out research specifically to determine whether their product could cause the injury Plaintiff sustained, nor at what incidence it occurred, nor in what populations of foreseeable users this product created an increased risk.

112. Had the BEXTRA DEFENDANTS conducted adequate testing prior to launching Bextra, the scientific data would have revealed significant increases in the risk of stroke and

heart attacks amongst the intended population of Bextra consumers.

113. In fact, post-marketing data has revealed increased risks of clotting, stroke and myocardial infarction, but that information was intentionally suppressed by the BEXTRA DEFENDANTS in order for the BEXTRA DEFENDANTS to gain significant profits from Bextra sales.

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114. At all times up until the Plaintiff was injured, the BEXTRA DEFENDANTS were aware that their product could cause serious skin reactions including Stevens Johnson Syndrome, Toxic Epidermal Necrolysis (TENS), and Erythema Multiforme, and did not adequately inform the Food and Drug Administration, the medical profession, the physician who prescribed the drug, Plaintiff, the pharmacy where the prescription was filled, or the consuming public that Bextra could cause these life threatening injuries.

115. At all times up until Plaintiff was injured, the BEXTRA DEFENDANTS did not include any contradictions in its labeling as to certain types of persons who would be at higher risk in using Bextra, including those risk factors which Plaintiff had during the time that she ingested Bextra.

116. At all times up until Plaintiff was injured, the BEXTRA DEFENDANTS were aware of but concealed from Plaintiff, the Food and Drug Administration, the medical profession, the physician who prescribed the drug, the pharmacy where the prescription was filled, and the consuming public that Bextra could cause serious skin reactions including Stevens Johnson Syndrome, Toxic Epidermal Necrolysis (TENS), and Erythema Multiforme and that there were certain users who were at an increased risk of having that injury occur.

117. The BEXTRA DEFENDANTS' failure to conduct adequate testing and/or additional testing prior to its market launch was based upon the BEXTRA DEFENDANTS'

desire to generate maximum financial gains for itself and to gain a significant market share in the highly competitive Cox-2 inhibitor market.

118. At the time that the BEXTRA DEFENDANTS manufactured, advertised, and distributed Bextra to consumers, the BEXTRA DEFENDANTS intentionally ignored and/or withheld information regarding the increased risks of life threatening skin and systemic reactions, hypertension, stroke and/or myocardial infarctions because the BEXTRA DEFENDANTS knew that if such increased risks were disclosed, consumers would not purchase Bextra.

119. At all times relevant hereto, the BEXTRA DEFENDANTS engaged in a marketing campaign with the intent that consumers would perceive Bextra as a safer and more efficacious drug than its competitors and, thereby, purchase Bextra.

120. The BEXTRA DEFENDANTS widely and successfully marketed Bextra throughout the United States by, among other things, conducting promotional campaigns that misrepresented the efficacy of Bextra in order to induce widespread use and consumption. Bextra was represented to relieve the pain and discomfort of arthritis, osteoarthritis, and related problems. The BEXTRA DEFENDANTS made misrepresentations through product inserts, advertising, detailing, promotional materials, and other aggressive marketing efforts.

121. The BEXTRA DEFENDANTS failed to perform adequate testing. Adequate testing would have shown that Bextra possessed serious side effects. The BEXTRA DEFENDANTS should have taken appropriate measures to ensure that its defectively designed product would not be placed into the stream of commerce and/or should have provided full and proper warnings that accurately and fully reflected the scope and severity of those side effects.

122. Prior to the manufacturing, sale, and distribution of Bextra, the BEXTRA

DEFENDANTS, through its officers, directors, and managing agents, had notice and knowledge from several sources that Bextra presented substantial and unreasonable risks of harm to the consumer. As such, Bextra consumers, including Plaintiff, were unreasonably subjected to risk of injury or death from the ingestion of Bextra.

123. In addition, the BEXTRA DEFENDANTS had notice from numerous sources that Cox-2 inhibitors as a whole might present unreasonable risks of harm to consumers based upon various studies that had been published with regard to Vioxx and even its own Cox-2 inhibitor, Celebrex. Rather than heed these warnings, the BEXTRA DEFENDANTS instead chose to attempt to capitalize on negative news about Vioxx in hopes of selling more Bextra.

124. Despite such knowledge, the BEXTRA DEFENDANTS, through its officers, directors, and managing agents for the purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to remedy the known defects of Bextra, and failed to warn the public, including Plaintiff, of the serious risk of injury occasioned by the defects inherent in the formulation of Bextra. The BEXTRA DEFENDANTS and its officers, agents and managers intentionally proceeded with the manufacturing, sale, and marketing of Bextra, knowing that persons would be exposed to serious potential dangers in order to advance their own pecuniary interests.

125. At all times up until Plaintiff was injured, the BEXTRA DEFENDANTS were aware of but concealed from Plaintiff, the Food and Drug Administration, the medical profession, the physician who prescribed the drug, the pharmacy where the prescription was filled, and the consuming public that the pain for which Plaintiff ingested Bextra could be treated as effectively, more safely, and cheaply by over-the-counter NSAID drugs.

126. In January of 2005, the FDA issued a letter reprimanding the BEXTRA DEFENDANTS for their false and misleading marketing of its products, including Bextra. The letter advised the BEXTRA DEFENDANTS that its marketing schemes "omit material facts, including the indication and risk information; fail to make adequate provision for the dissemination of the FDA-approved product labeling; and make misleading safety, unsubstantiated superiority, and unsubstantiated effectiveness claims" and "therefore [are] in violation of the Federal Food, Drug, and Cosmetic Act (Act) and FDA implementing regulations." The FDA called upon the BEXTRA DEFENDANTS to "immediately cease the dissemination of promotional materials" for Bextra.

127. On April 7, 2005, Bextra was removed from the market. According to an FDA Public Health Advisory, Bextra was taken off the market for three reasons:

- a. increased risk of heart attack and stroke;
- b. increased risk of serious and life threatening skin reactions; and
- c. there was no advantage associated with Bextra when compared with other cheaper and safer NSAIDs.

128. The BEXTRA DEFENDANTS promoted the sale of Bextra by misleading users about the efficacy of the product and by failing to adequately warn users (including Plaintiff) and prescribing physicians of the serious dangers which the BEXTRA DEFENDANTS knew or should have known were associated with the use of Bextra, including an increased risk of adverse cardiovascular events and severe skin reactions.

129. The BEXTRA DEFENDANTS failed to perform adequate pre-marketing and post-marketing testing of Bextra and likewise failed to thoroughly and objectively analyze and/or report the data generated by the testing it conducted. In promoting Bextra to the medical community, the FDA, and the general public, the BEXTRA DEFENDANTS systematically

minimized the risks suggested by clinical data while overstating the alleged efficacy and purported safety of Bextra. Adequate testing and objective reporting of those tests conducted would have demonstrated and revealed to the public and medical community the increased risk of cardiovascular events and severe skin reactions associated with the ingestion of Bextra.

130. At the time the BEXTRA DEFENDANTS manufactured, advertised, and distributed the BEXTRA DEFENDANTS to consumers including Plaintiff, the BEXTRA DEFENDANTS intentionally or recklessly ignored and/or withheld information regarding the increased risks of serious skin reactions, hypertension, stroke and/or myocardial infarctions because the BEXTRA DEFENDANTS knew that if such increased risks were disclosed, consumers would not purchase Bextra, but instead would purchase other cheaper and safer NSAID drugs.

131. The BEXTRA DEFENDANTS misrepresented the safety and effectiveness of Bextra to prescribing physicians, Plaintiff, scientific journals, and the consuming public, and concealed or understated the dangerous side effects associated with ingestion of Bextra. The BEXTRA DEFENDANTS also engaged in such aggressive, improper, and dishonest promotion to certain physicians that the prescribing physicians were no longer able to make independent decisions as a learned intermediary on behalf of their patients.

132. The BEXTRA DEFENDANTS engaged in a pattern of reckless behavior and manipulation with regard to the promotion and sale of Bextra in a successful effort to enhance profits at the expense of the public health.

133. As a direct result of the BEXTRA DEFENDANTS' misconduct, the Plaintiff was prescribed and ingested Bextra and suffered significant harm.

134. Plaintiff used Bextra as prescribed and in a foreseeable manner.

135. Plaintiff ingested Bextra that was in a condition substantially identical to the condition in which it was manufactured and sold.

136. Plaintiff would not have ingested Bextra had the BEXTRA DEFENDANTS properly disclosed the risks associated with the drug.

137. As a direct and proximate result of the defective condition of the Bextra manufactured and marketed by the BEXTRA DEFENDANTS and ingested by Plaintiff, Plaintiff has suffered and continues to suffer from serious injuries, including, but not limited to, pain and suffering, physical injuries, disability, disfigurement, embarrassment, mental anguish, loss of capacity for the enjoyment of life, expenses of hospitalization, medical, nursing care and treatment, loss of earnings, loss of the ability to earn money in the future, and a shortened life span.

### **C. Factual Background Relating To CELEBREX DEFENDANTS**

138. This action arises out of the CELEBREX DEFENDANTS' manufacturing, selling, distributing, marketing and/or otherwise promoting Celebrex in the State of Florida without proper warnings as to the dangers associated with its use.

139. The pharmaceutical drug Celebrex, manufactured by the CELEBREX DEFENDANTS, is defective, dangerous to human health, and unfit and unsuitable to be marketed and sold in commerce.

140. At all times material hereto, PFIZER and/or its predecessors in interest were engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and selling the drug Celcoxib under the trade name Celebrex in Florida and throughout the United States.

141. At all times material hereto, SEARLE has been engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and selling the drug Celecoxib under the trade name Celebrex in Florida and throughout the United States.

142. At all times material hereto, PHARMACIA and its predecessors in interest have been engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and selling the drug Celecoxib under the trade name Celebrex in Florida and throughout the United States.

143. At all times material hereto, MONSANTO, through its subsidiary companies, was in the business of manufacturing, marketing, selling, and distributing the pharmaceutical product Celebrex in Florida and throughout the United States.

144. Celecoxib was developed in 1998 by SEARLE and marketed jointly by SEARLE and PFIZER under the brand name Celebrex. SEARLE was acquired by PHARMACIA, which was then acquired by PFIZER, in part so that PFIZER could take full control of Celebrex.

145. At all times relevant to this action, the CELEBREX DEFENDANTS intentionally, recklessly and/or negligently concealed, suppressed, omitted, and misrepresented the risks, dangers, defects and disadvantages of Celebrex, and advertised, promoted, marketed, sold, and distributed Celebrex as a safe prescription medication when, in fact, the CELEBREX DEFENDANTS had reason to know, and did know, that Celebrex was not safe for its intended purposes, for the patients for whom it was prescribed, and for whom it was sold; and that Celebrex caused serious medical problems, and in certain patients, catastrophic injuries and deaths.

146. In engaging in the conduct alleged herein, the CELEBREX DEFENDANTS each acted as the agent for each of the other CELEBREX DEFENDANTS or their Defendant's predecessors in interest.

147. At all times material herein, the CELEBREX DEFENDANTS were in the business of designing, manufacturing, marketing, developing, testing, labeling, promoting, distributing, warranting, and selling their product, Celebrex.

148. The CELEBREX DEFENDANTS designed, developed, manufactured, promoted, marketed, distributed, tested, warranted, and sold Celebrex in the State of Florida. The CELEBREX DEFENDANTS conduct substantial business in the State of Florida and advertise in Florida, receive substantial compensation and profits from sales of Celebrex in this state, and made material omissions and misrepresentations and breaches of warranties in Florida so as to subject them *in personam* jurisdiction in Florida. In engaging in the conduct alleged herein, each Celebrex Defendant acted as the agent for each of the other Defendants or their predecessors in interest.

149. On June 29, 1998, SEARLE and PFIZER filed for FDA approval of Celecoxib, its first major COX-2 inhibitor drug, under the trade name CELEBREX. The FDA granted preliminary approval of the new drug on December 31, 1998, for the relief of signs and symptoms of adult osteoarthritis and rheumatoid arthritis. A year later, on December 23, 1999, the FDA granted accelerated approval of CELEBREX for a second indication - the reduction of intestinal polyps as an adjunct to endoscopy and surgery in patients with familial adenomatous polyposis (FAP), a rare genetic disorder.

150. In late January of 1999, following FDA approval, PFIZER publicly launched CELEBREX, their new "blockbuster" drug, in one of the largest direct-to-consumer marketing

campaigns ever undertaken for prescription drugs. The CELEBREX DEFENDANTS' massive marketing campaign fraudulently and misleadingly depicted Celebrex as a much safer and more effective pain reliever than less inexpensive traditional NSAIDs. The Celebrex Defendants and their sales representatives and agents misrepresented the safety profile of Celebrex to consumers, the medical community, healthcare providers, and third party payors.

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151. The potential for cardiovascular risk of selective COX-2 inhibitors was known to the CELEBREX DEFENDANTS long before the FDA granted market approval in December 1998. By 1997, and prior to the submission of the New Drug Application (the "NDA") for Celebrex, CELEBREX DEFENDANTS were aware that, by selectively inhibiting only the COX-2 enzyme, Celebrex altered the homeostatic balance between prostacyclin synthesis and thromboxane and thereby increased the prothrombotic effects of Celebrex, causing blood clots to form in those who ingested it.

152. Early FDA updates in March and April of 1999 similarly acknowledged this known risk, but noted, based upon the CELEBREX DEFENDANTS' representations, that Celebrex "does not affect platelet aggregation (clumping), an important part of the blood clotting process."

153. Based on the studies performed on Celebrex, other COX-2 inhibitors including Vioxx, and basic research on this type of selective inhibitor which had been widely conducted, the CELEBREX DEFENDANTS knew when Celebrex was being developed and tested that selective COX-2 inhibitors posed serious cardiovascular risks for anyone who took them, and presented a specific additional threat to anyone with pre-existing heart disease or cardiovascular risk factors.

154. Despite years of studies on selective COX-2 inhibitors, as well as the disturbing new studies specifically analyzing the risks of Celebrex, the CELEBREX DEFENDANTS failed to take any action to protect the health and welfare of patients, opting instead to continue promoting Celebrex for sale even after the FDA's Drug Safety and Risk Management Advisory Committee and Arthritis Drug Advisory Committee meetings.

155. In September of 1998, PHARMACIA sponsored an allegedly independent Celebrex Long-Term Arthritis Safety Study ("CLASS"). The multicenter, double-blind, parallel group study sought to compare the incidence of clinically significant upper gastrointestinal events between Celebrex 400 mg bid and Ibuprofen 800 mg.

156. On September 13, 2000, the CELEBREX DEFENDANTS released the results of the CLASS study in the *Journal of the American Medical Association (JAMA)*. Researchers enthusiastically reported a "lower incidence of symptomatic ulcers and ulcer complications combined, as well as other clinically supported toxic effects, compared with NSAIDs at standard doses."

157. Although the CELEBREX DEFENDANTS touted the CLASS study as primary evidence to support its theory that Celebrex was safer for consumers who could not tolerate traditional NSAIDs in their gastrointestinal system, the CELEBREX DEFENDANTS intentionally, recklessly and/or negligently concealed, suppressed, omitted, and misrepresented the results, risks and defects of the CLASS study. Among other things, Defendants failed to release the study's complete twelve month results and instead released only the first six months of trials, reported biased and misleading results, limited conclusions to upper gastrointestinal events despite other known risks factors, and understated known cardiovascular risks.

158. Despite the CELEBREX DEFENDANTS' favorable CLASS Study conclusions, no other reviewing or administrative body was able to substantiate those findings. The FDA Medical Officer Review of the CLASS data in June of 2000 found Celebrex to be no more efficacious than other traditional NSAIDS comparators.

159. The FDA Arthritis Advisory Committee in February of 2001 similarly found no "clinically meaningful" safety advantage of Celebrex over older NSAIDs. The CLASS Study failed to demonstrate a superior safety record over ibuprofen or pooled NSAID data. Based on this information, the FDA Arthritis Advisory Committee advised that further studies needed to be done in order to assess the risk of COX-2 drugs and NSAIDS when taken with aspirin.

160. In a June of 2002 editorial, the *British Medical Journal* chastised the CLASS Study's "misleading" and "seriously biased" nature, noting that the complete results "clearly contradict[ed] the published conclusions" and warned against the dangers of "overoptimistic," "short-term" data and "post hoc changes to the protocol." Most noticeably, the CLASS study considered only six months of data despite the fact that researchers at that point had twelve months of data that, when analyzed as a whole, showed no significant difference. Instead of releasing the complete twelve month results from CLASS, the CELEBREX DEFENDANTS relied on and published only the first six months of data. The results of the completed study revealed the real truth: Celebrex offered no gastrointestinal (GI) benefit. Almost all ulcer-related complications that had occurred during the second half of the CLASS trials were in users of Celebrex. These results clearly contradict the published CLASS conclusions and representations made by the CELEBREX DEFENDANTS regarding the safety and efficacy of Celebrex.

161. Editors of the Journal of the American Medical Association (JAMA) and other medical experts were reportedly "flabbergasted" in 2001 when they realized they had been "duped" by the CELEBREX DEFENDANTS by only being provided with the first six months of CLASS data. The *Washington Post* reported JAMA editors noting: "When all of the data were considered, most of Celebrex's apparent [GI] safety advantage disappeared."

162. Institutional bias also appeared to play a role in the CLASS Study's biased conclusions. According to the *Washington Post*, all sixteen CLASS authors were either employees of the CELEBREX DEFENDANTS or paid consultants. Moreover, at least one author, Dr. M. Michael Wolfe, a gastroenterologist from Boston University, admits he was duped by the CELEBREX DEFENDANTS. In the Summer of 2000, Dr. Wolfe was asked to participate in the "six-month" trial. Wolfe found the study, tracking 8,000 patients over a six-month period, persuasive, and penned a favorable review, which helped to drive up Celebrex sales. It was not until early the next year, while serving on the FDA's Arthritis Advisory Committee, that Wolfe learned the study had run for one year, not six months, as the company

had originally led both Wolfe and JAMA to believe. Here again, when the complete data was considered, most of Celebrex's advantages disappeared.

163. The CELEBREX DEFENDANTS also limited conclusions of the CLASS study to upper gastrointestinal events, despite other known risks factors and understated known cardiovascular risks including a higher incidence of heart attacks in users of Celebrex. A 2001 Case 8:07-cv-00897-SDM-MAP Document 2 Filed 05/24/2007 Page 38 of 5 metastudy of cardiovascular risks by the Cleveland Clinic published in JAMA analyzed data from two major studies (including CLASS) that were funded by the drug companies and two smaller ones. The metastudy found that the CELEBREX DEFENDANTS and MERCK failed to identify and study cardiovascular risks associated with for their respective products. The Cleveland Clinic researchers found that the annualized heart attack rates for patients taking Vioxx or Celebrex were "significantly higher" than those in a group taking placebos and that the available data raised a cautionary flag about the risk of cardiovascular events associated with Cox-2 inhibitors.

164. Public Citizen, a public watchdog organization, also reviewed the CLASS data in its entirety and concluded that the rate of heart attacks in patients using Celebrex was double that of the other two NSAIDs studied.

165. Dr. Eric Topol of the Cleveland Clinic reached a similar conclusion, noting that the CLASS trial MI rate was 1.6% in the Celebrex group (at a dosage of 400 mg twice a day) and 1.2% in the ibuprofen group for the 1,739 patients taking low-dose aspirin. Dr. Topol noted that this numerical excess, albeit not statistically significant, was also found in the 6,229 patients not taking aspirin in the trial. Based on this data, Dr. Topol and his colleagues concluded: "It is mandatory to conduct a trial specifically assessing cardiovascular morbidity." Unfortunately, no such trials were ever initiated by the CELEBREX DEFENDANTS resulting in a delay in safety warnings regarding Celebrex that jeopardized countless lives in the process.

166. The CLASS data proves that the CELEBREX DEFENDANTS knew that its first generation COX-2 inhibitor, Celebrex, caused a disproportionately and statistically significant excess number of adverse cardiovascular events before it was introduced to the market in

January of 1999.

167. In early 2000, the National Cancer Institute (NCI), in collaboration with SEARLE and PFIZER, initiated the Adenoma Prevention with Celecoxib (APC) trial, a randomized, double-blind, placebo-controlled study to determine the efficacy of Celebrex in preventing the growth of pre-cancerous colon polyps. The trial involved 2,026 patients across the country with randomization to one of three groups: (1) placebo; (2) 200 mg Celebrex twice daily; and (3) 400 mg Celebrex twice daily. The patients, each of whom had an adenomatous polyp removed before enrollment, were followed up for a mean of 33 months while taking the study drug, with the primary objective of limiting the development of colorectal cancer.

168. On December 17, 2004, the National Cancer Institute suspended the use of Celebrex for all participants in the APC trial due to a “significant excess of cardiovascular death, myocardial infarction (MI) and stroke.” Analysis by an independent Data Safety Monitoring Board (DSMB) showed a two to three-fold increased risk of major fatal and non-fatal cardiovascular events for participants taking Celebrex compared to those on a placebo.

169. The absolute excess of major cardiovascular events of 13/1000 patients at the Celebrex 800 mg dose (400 mg 2x day) was strikingly similar to the results of trials with Vioxx and Bextra, both selective NSAID COX-2 inhibitors removed from the market due to their significant cardiovascular risks.

170. On April 7, 2005, the FDA reported similar results with regard to the APC trial:

In the National Cancer Institute’s Adenoma Prevention with Celecoxib (APC) trial in patients at risk for recurrent colon polyps, a 2-3 fold increased risk of serious adverse CV events was seen for Celebrex compared to placebo after a mean duration of treatment of 33 months. There appeared to be a dose response relationship, with a hazard ratio of 2.5 for Celebrex 200 mg twice daily and 3.4 Celebrex 400 mg twice daily for the composite endpoint of death from CV causes, myocardial infarction (MI), or stroke.

171. The dosage noted in the study is itself important for two reasons: (1) there appears to be an association between dosage and an increase in adverse cardiovascular events and (2) most patients are expected to increase dosage (a phenomenon known as "dosage creep"). The CELEBREX DEFENDANTS knew patients were increasing their dosages as noted in the CLASS Study.

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172. Several other Celebrex trials also gave the CELEBREX DEFENDANTS notice of the cardiovascular risks presented by Celebrex. The Prevention of Spontaneous Adenomatous Polyps (PreSAP) trial identified the death rate from cardiovascular causes (heart attack, stroke, heart failure, angina, or need for CV procedure) as 3.6% with Celebrex as compared to 2.7% for placebo.

173. Public Citizen also reviewed the results of Study IQ IQ5-97-02-001 which reflected "the combined rate of all serious cardiovascular adverse events in patients getting a placebo was 2.1% but was greatly increased in those getting celecoxib [Celebrex] to 7.7%, a 3.6 fold increase in CV risk in those people taking celecoxib. (p=0.03)." According to Dr. Sidney Wolfe of Public Citizen, in January of 2005, the "study revealed a significantly increased rate (3.6-fold) of serious CV adverse events and more than a doubling in the rate of CV deaths in people using celecoxib [Celebrex] compared to those using placebo."

174. The CELEBREX DEFENDANTS also had access to other data which indicated a cardiovascular risk associated with Celebrex and other Cox-2 inhibitors. Specifically, the CELEBREX DEFENDANTS had knowledge of two studies conducted by MERCK related to Vioxx – Vioxx Gastrointestinal Outcomes Research (VIGOR) and Adenomatous Polyp Prevention (APPROVe).

175. In 2000, the FDA Medical Officer Review of CLASS specifically noted the VIGOR trial and the concern over serious adverse cardiovascular events.

176. According to VIGOR, Vioxx patients experienced: 20% more serious clinical adverse events, 4.6 times more hypertension events serious enough to warrant discontinuation; 1.7 times more edema events; and 1.85 times as many congestive heart failure adverse events. By two measures of cardiovascular events related to blood clots, Vioxx had twice the risk of naproxen and the results were considered statistically significant.

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177. The VIGOR study comprised the most definitive scientific evidence ever obtained about pharmaceutical products. It was a large, randomized clinical trial (the "gold standard" of medical research). It was a safety study with endpoints set in advance. As MERCK stated many times, it was designed to provide definite proof of safety, convincing enough to silence the most skeptical critics. In medical terms, the VIGOR results raised the question of whether selective inhibition of COX-2 was a monumental mistake from the start. While the NSAID risks to the GI system were real and sometimes fatal, they were dwarfed by the cardiovascular risks faced by arthritis patients who ingested Cox-2 drugs such as Vioxx or Celebrex on a daily basis. All makers of NSAIDs, including the CELEBREX DEFENDANTS, were aware of these results.

178. Anxious to put safety questions surrounding Vioxx to rest, MERCK designed another large scale trial, Adenomatous Polyp Prevention (APPROVe), which was intended to test Vioxx's ability to prevent or shrink colon polyps, but would also compare the cardiovascular safety of Vioxx to a placebo control. According to the analysis conducted by Public Citizen in January of 2005 of the APPROVe data, Vioxx "doubled the risk of any thrombotic cardiovascular event" and "doubled the risk of MI (myocardial infarction a/k/a heart attack)<sup>1</sup>. Despite the available Celebrex data and other red flags related to Vioxx, the CELEBREX DEFENDANTS never paused to reevaluate the Celebrex data and studies and heed these significant significant signals of safety risks.

179. The scientific data available during and after Celebrex's approval made clear to

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<sup>1</sup> Although MERCK claims that the two-fold risk of heart attacks and strokes seen in the APPROVe trial did not emerge until after patients had been taking the drug for 18 months, closer analysis indicates that a significant increase in risk of heart attack was evident in as little as 4 months time.

the CELEBREX DEFENDANTS that their formulation of Celebrex would cause a higher risk of blood clots, stroke and/or myocardial infarctions among Celebrex consumers, alerting the CELEBREX DEFENDANTS to the need to do additional and adequate safety studies.

180. Based upon readily available scientific data, the CELEBREX DEFENDANTS knew, or should have known, that their pre-approval testing of Celebrex did not adequately represent the cross-section of individuals who were intended consumers and therefore, likely to take Celebrex. Therefore, the CELEBREX DEFENDANTS' testing and studies were grossly inadequate.

181. Had the CELEBREX DEFENDANTS done adequate testing prior to approval and market launch (rather than the extremely short duration studies on the small size patient base that were actually completed), the scientific data would have revealed significant increases in the incidence of strokes and myocardial infarctions among the intended and targeted population of Celebrex consumers. Adequate testing would have shown that Celebrex possessed serious side effects. The CELEBREX DEFENDANTS should have taken appropriate measures to ensure that their defectively designed product would not be placed in the stream of commerce and/or should have provided full and proper warnings accurately and fully reflecting the scope and severity of symptoms of those side effects should have been made.

182. In fact, post-market approval data did reveal increased risks of clotting, stroke and myocardial infarction, but the CELEBREX DEFENDANTS intentionally suppressed this information in order for them to gain significant profits from continued Celebrex sales.

183. The CELEBREX DEFENDANTS' failure to conduct adequate testing and/or additional testing prior to market launch was based upon their desire to generate maximum financial gains for themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

184. At the time the CELEBREX DEFENDANTS manufactured, advertised, and distributed Celebrex to consumers, the CELEBREX DEFENDANTS intentionally or recklessly

ignored and/or withheld information regarding the increased risks of hypertension, stroke and/or myocardial infarctions because the CELEBREX DEFENDANTS knew that if such increased risks were disclosed, consumers would not purchase CELEBREX, but instead would purchase other cheaper and safer NSAIDs that were not cox-2 inhibitors.

185. Such an ineffective and unreasonably dangerous drug could only be widely prescribed as a result of a tremendous marketing campaign. In addition to being aggressive, the CELEBREX DEFENDANTS' marketing campaign was fraudulent and misleading. But for fraudulent and misleading advertising, consumers, including the Plaintiff, would not have purchased Celebrex, a more costly prescriptive drug, ineffective for its intended purposes. Case 8:07-cv-00897-SDM-MAP Document 2 Filed 05/24/2007 Page 43 of 5

186. The CELEBREX DEFENDANTS' marketing was so fraudulent that the FDA issued three Warning Letters to Defendants in October 1999, April 2000, and November 2000, all finding that the CELEBREX DEFENDANTS were unlawfully making false or misleading statements concerning the safety and/or efficacy of Celebrex. The November letter cited two direct-to-consumer television advertisements that overstated the efficacy of Celebrex. The FDA ordered that the CELEBREX DEFENDANTS immediately cease distribution of the misleading ads.

187. On February of 2001, the FDA issued a Warning Letter to the CELEBREX DEFENDANTS stating that promotional activities from marketing Celebrex were unlawful because they were "false, lacking in fair balance, or otherwise misleading." The FDA found that Celebrex had been promoted for unapproved uses, in unapproved dosing regimens, and that the marketers had made unsupportable claims that Celebrex was safer and more effective than other NSAIDs.

188. On January 10, 2005, the FDA again issued the CELEBREX DEFENDANTS a written reprimand for its promotional activities. The reprimand reads: "These five promotional pieces [3 Celebrex and 2 Bextra] variously: omit material facts ... and make misleading safety, unsubstantiated superiority, and unsubstantiated effectiveness claims." Amid continued

frustration with the CELEBREX DEFENDANTS continually misleading marketing strategy and ever surmounting evidence of cardiovascular dangers, the FDA Advisory Panel voted overwhelmingly that the company should never again advertise the drug [Celebrex].”

189. At all times relevant herein, the CELEBREX DEFENDANTS engaged in a marketing campaign with the intent that consumers would perceive Celebrex as a safer and better drug than other NSAIDs and, therefore, purchase Celebrex.

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190. The CELEBREX DEFENDANTS widely and successfully marketed Celebrex throughout the United States by, among other things, conducting promotional campaigns that misrepresented the efficacy of Celebrex in order to induce a widespread use and consumption. Celebrex was represented to aid the pain and discomfort of arthritis, osteoarthritis, and related problems. The CELEBREX DEFENDANTS made misrepresentations by means of media advertisements, and statements contained in sales literature provided to Plaintiff's prescribing physicians, fraudulent detailing by its sales force, misleading publications in medical journals, improper statements in CME and other funded conferences, and improper influence (financial and otherwise) of prescribing physicians.

191. The CELEBREX DEFENDANTS misrepresented the safety and effectiveness of Celebrex to prescribing physicians, Plaintiff, scientific journals, and the consuming public, and concealed or understated the dangerous side effects associated with ingestion of Celebrex. The CELEBREX DEFENDANTS also engaged in such aggressive, improper, and dishonest promotion to certain physicians such that the prescribing physicians were no longer able to make independent decisions as a learned intermediary on behalf of patients.

192. In an elaborate and sophisticated manner, the CELEBREX DEFENDANTS aggressively marketed Celebrex directly to consumers and medical professionals (including physicians and leading medical scholars) in order to leverage pressure on third party payors, medical care organizations, and large institutional buyers (e.g., hospitals) to include Celebrex on their formularies. Faced with the increased demand for Celebrex by consumers and health care professionals that resulted from the CELEBREX DEFENDANTS' successful advertising and

marketing blitz, third party payors were compelled to add Celebrex to their formularies. The CELEBREX DEFENDANTS' marketing campaign specifically targeted third party payors, physicians, and consumers, and was designed to convince them of both the therapeutic and economic value of Celebrex.

193. The CELEBREX DEFENDANTS represented that Celebrex had a similar efficacy and safety profile as ibuprofen and naproxen but was superior because it lacked any of the common gastrointestinal adverse side effects associated with these and other non-steroidal anti-inflammatory drugs ("NSAIDs"). The CELEBREX DEFENDANTS promoted Celebrex as a safe and effective alternative that would not have the same deleterious and painful impact on the gut, but that would be just as effective, if not more so, for pain relief.

194. Yet, Celebrex possessed dangerous and concealed or undisclosed side effects, including the increased risk of serious cardiovascular events, such as heart attacks, unstable angina, cardiac clotting, hypertension, and cerebrovascular events, such as strokes. In addition, Celebrex, which is significantly more expensive than traditional NSAIDs<sup>2</sup>, was actually no more effective than traditional and less expensive NSAIDs and, just like traditional NSAIDs, carried a risk of perforations, ulcers, and gastrointestinal bleeding. Yet, the CELEBREX DEFENDANTS chose not to warn about these risks and dangers.

195. The CELEBREX DEFENDANTS knew of these risks before the U.S. Food and Drug Administration (the "FDA") approved Celebrex for sale, but they ignored, downplayed, suppressed, omitted, and concealed these serious safety risks and denied inefficacy in its promotion, advertising, marketing, and sale of Celebrex. The CELEBREX DEFENDANTS' omission, suppression, and concealment of this important information enabled Celebrex to be sold to, and purchased, or paid for by consumers at a grossly inflated price.

196. Consequently, Celebrex gained a large market share in the highly lucrative market for arthritis and analgesic medications. According to Searle, more than 27 million prescriptions

have been written for Celebrex since its approval on December 31, 1998. The CELEBREX DEFENDANTS spent more than \$70 million for extensive direct-to-consumer advertising in 2004, making Celebrex one of the company's top selling drugs. From the period from 2002-2004, Celebrex earned \$5.28 billion in revenue.

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197. Because the CELEBREX DEFENDANTS engaged in a promotional and marketing campaign that featured an advertising blitz directly targeted to consumers, that touted Celebrex as a safer drug than other drugs in its class, while uniformly failing to disclose the health risks of Celebrex, Defendants were able to justify pricing Celebrex significantly higher than the cost of generic aspirin. In reality, that price inflation was not justified. Had the CELEBREX DEFENDANTS disclosed the truth about Celebrex, they would not and could not have reaped the billions of dollars in CELEBREX sales that were achieved as a direct result of the concealment, omission, suppression, and obfuscation of the truth.

198. The CELEBREX DEFENDANTS intentionally, deliberately, knowingly, and actively concealed, omitted, suppressed, and obfuscated important and material information regarding the risks, dangers, defects, and disadvantages of Celebrex from Plaintiff, the public, the medical community, and others. This concealment and omission was deliberate, knowing, active, and uniform, was intended to induce and maximize sales and purchases of Celebrex, and prevented Plaintiff from obtaining all the material information that would be important to his decision as a reasonable person to purchase, pay for, and/or use Celebrex.

199. The CELEBREX DEFENDANTS' systematic, active, knowing, deliberate, and uniform concealment, omissions, suppression, and conduct caused Plaintiff to purchase, pay for, and/or use Celebrex; and caused Plaintiff's losses and damages as asserted herein.

200. Had the CELEBREX DEFENDANTS performed adequate testing prior to approval and "market launch," the scientific data would have revealed significant increases in

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2 The cost of Celebrex is at least \$3-\$6 per day, while an over-the-counter NSAID can cost \$.50 or less per day.

stroke and myocardial infarctions amongst the intended population of Celebrex consumers. Adequate testing would have shown that Celebrex possessed serious side effects. The CELEBREX DEFENDANTS should have taken appropriate measures to ensure that their defectively designed product would not be placed into the stream of commerce and/or should have provided full and proper warnings that accurately and fully reflected the scope and severity of adverse effects associated with Celebrex.

201. In fact, post-market approval data did reveal increased risks of clotting, stroke and myocardial infarction, but the CELEBREX DEFENDANTS intentionally suppressed this information in order for them to gain significant profits from continued Celebrex sales.

202. The CELEBREX DEFENDANTS' failure to conduct adequate testing and/or additional testing prior to "market launch," and active concealment and failure to warn the medical community and general public of the known cardiovascular risks of Celebrex was particularly negligent, reckless and/or malicious given the drug's known target market. The CELEBREX DEFENDANTS were well aware that most patients taking Celebrex are elderly and have higher risk of developing cardiovascular risks to begin with. Nearly half of the patients with arthritis have coexisting cardiovascular disease, and most patients, as discovered in the CLASS study, were prone to higher dosing.

203. The CELEBREX DEFENDANTS' failure to conduct adequate testing and/or additional testing prior to "market launch" was based upon their desire to generate maximum financial gains for the CELEBREX DEFENDANTS and to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

204. At the time that the CELEBREX DEFENDANTS manufactured, advertised, and distributed Celebrex to consumers including Plaintiff, the CELEBREX DEFENDANTS intentionally or recklessly ignored and/or withheld information regarding the increased risks of hypertension, stroke and/or myocardial infarctions because the CELEBREX DEFENDANTS knew that if such increased risks were adequately disclosed, consumers would not purchase Celebrex, but instead would purchase other cheaper and safer NSAID drugs.

205. The CELEBREX DEFENDANTS misrepresented the safety and effectiveness of Celebrex to prescribing physicians, Plaintiff, scientific journals, and the consuming public, and concealed or understated the dangerous side effects associated with ingestion of Celebrex. The CELEBREX DEFENDANTS also engaged in such aggressive, improper, and dishonest promotion to certain physicians that the prescribing physicians were no longer able to make independent decisions as a learned intermediary on behalf of their patients.

206. As a direct and legal result of the defective condition of the Celebrex manufactured and marketed by the CELEBREX DEFENDANTS and ingested by Plaintiff, Plaintiff has suffered and continues to suffer from serious injuries, including, but not limited to, pain and suffering, physical injuries, disability, disfigurement, embarrassment, mental anguish, loss of capacity for the enjoyment of life, expenses of hospitalization, medical, nursing care and treatment, loss of earnings, loss of the ability to earn money in the future, and a shortened life span.

## COUNT I

### **STRICT LIABILITY (as to all Defendants)**

Plaintiff adopts by reference all of the allegations contained in Paragraphs 1 through 206 above, each inclusive, as though fully set forth herein, pursuant to Rule 1.130(b), Florida Rules of Civil Procedure.

207. The Vioxx, Celebrex and Bextra ingested by Plaintiff were defective and unreasonably dangerous when it left the possession of MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS in that:

- a. When placed in the stream of commerce, Vioxx, Celebrex and Bextra contained unreasonably dangerous design defects and were not reasonably safe as intended to be used, subjecting Plaintiff to risks which exceeded the benefits of the drugs;

- b. When placed in the stream of commerce, Vioxx, Celebrex and Bextra were defective in design and formulation, making use of the drugs more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with Plaintiff's ailment;
- c. Vioxx, Celebrex and Bextra contained insufficient warnings to alert Plaintiff, consumers, and prescribing physicians of severe and life threatening complications and side effects including, but not limited to ~~Castrol thrombus~~,  
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- d. There was misleading advertising and promotion concerning the benefits of using Vioxx, Celebrex and Bextra;
- e. There were inadequate post-marketing warnings or instructions for Vioxx and Bextra because, after MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS knew or should have known of the significant risks associated with the use of Vioxx, Celebrex and Bextra, MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS failed to provide adequate warnings to Plaintiff, consumers, and prescribing physicians, and continued to aggressively promote and advertise direct-to-consumers the sale and use of Vioxx, Celebrex and Bextra; and
- f. The Vioxx, Celebrex and Bextra ingested by Plaintiff had not been materially altered or modified prior to use.

208. Plaintiff used Vioxx, Celebrex and Bextra for their intended purpose of pain management.

209. MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS, as manufacturers of prescription drugs, are held to the level of knowledge of an expert in the field.

210. Plaintiff's prescribing physician did not have substantially the same knowledge as MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS, or the level of knowledge that would have been gleaned from an adequate warning from MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS.

211. The warnings that were given by MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS to prescribing physicians, consumers, and Plaintiff were not accurate, clear, and/or unambiguous.

212. MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS had a continuing duty to warn the Plaintiff, consumers, and prescribing physicians of the dangerous risks and reactions associated with Vioxx, Celebrex and Bextra.

213. Plaintiff could not have discovered any defect in the product through the exercise of care.

214. As a direct and legal result of the defective condition of Vioxx, Celebrex, and Bextra and their respective inadequate warnings, Plaintiff suffered serious personal injury, has sustained economic losses, and has expended (and/or may in the future be required to expend) fair and reasonable expenses for necessary health care, attention and services, and has and/or may incur incidental and related expenses.

WHEREFORE, Plaintiff demands judgment against MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS for damages, as well as costs of this action and a trial by jury of all issues to be tried.

## COUNT II

### **NEGLIGENCE (as to all Defendants)**

Plaintiff adopts by reference all the allegations contained in Paragraphs 1 through 206 above, each inclusive, as though fully set forth, pursuant to Rule 1.130 (b), Florida Rules of Civil Procedure.

215. At all times material hereto, MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS had a duty to Plaintiff to exercise reasonable care in the design,

manufacture, testing, processing, advertising, marketing, labeling, assembling, packaging, distribution and sale of Vioxx, Celebrex and Bextra.

216. MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS were negligent in their actions, misrepresentations, and omissions toward Plaintiff and Plaintiff's prescribing physician in the following ways:

- a. They failed to include adequate warnings with their respective drugs that would have alerted consumers and physicians to the potential risks and serious side effects of Vioxx, Celebrex, and Bextra;
- b. Failed to adequately and properly test Vioxx, Celebrex, and Bextra before placing the drugs on the market;
- c. Failed to provide adequate post-marketing warnings or instructions after MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS knew of the significant risks of personal injury and death as identified herein and other serious side effects resulting from the use of Vioxx, Celebrex and Bextra;
- d. Failed to adequately warn Plaintiff that Vioxx, Celebrex, and Bextra should not be used by patients with any risk factors for these adverse effects such as family history of ischemic heart disease, or risk factors for ischemic cardiovascular disease;
- e. Failed to adequately disclose and warn Plaintiff that Plaintiff undertook the risk of adverse events and death by ingesting Vioxx, Celebrex, and Bextra; and
- f. Failed to adequately and timely inform the health care industry of the risks of serious personal injury and death resulting from Vioxx, Celebrex, and Bextra ingestion as described therein.

217. MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS knew or should have known that Vioxx, Celebrex, and Bextra caused unreasonably dangerous risks and serious side effects of which Plaintiff was unaware. MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS nevertheless aggressively advertised,

marketed, sold and distributed Vioxx, Celebrex, and Bextra knowing that there were safer products and options for treatment of pain due to inflammation.

218. As a direct and legal result of the negligence of MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS, Plaintiff suffered serious injury, and Plaintiff seeks all damages allowed under the law.

WHEREFORE, Plaintiff demands judgment against MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS for damages, as well as costs of this action and a trial by jury of all issues to be tried.

### COUNT III

#### **NEGLIGENT MISREPRESENTATION (as to all Defendants)**

Plaintiff adopts by reference all of the allegations contained Paragraphs 1 through 206 above, each inclusive, as though fully set forth, pursuant to Rule 1.130 (b), Florida Rules of Civil Procedure.

219. MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS negligently misrepresented to Plaintiff and Plaintiff's prescribing physician the safety and effectiveness of Vioxx, Celebrex, and Bextra and/or negligently misrepresented material information regarding Vioxx, Celebrex, and Bextra and/or negligently misrepresented adverse information regarding the safety and effectiveness of the drugs Vioxx, Celebrex, and Bextra.

220. The negligent misrepresentations of MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS were communicated to Plaintiff's prescribing physician with the intent that they reach the Plaintiff, and that the effect of such representations would be that prescriptions would be written for Vioxx, Celebrex, and Bextra for the consuming public, including Plaintiff.

221. MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS misrepresented safety information regarding Vioxx, Celebrex, and Bextra with the intention and specific desire that Plaintiff, Plaintiff's prescribing physician, other dispensing entities, and the consuming public would rely on such information in selecting, requesting, or prescribing treatment.

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222. MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS misrepresented material, adverse information regarding the safety and effectiveness of Vioxx, Celebrex, and Bextra.

223. MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS made these misrepresentations and actively concealed adverse information at a time when MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS knew, or should have known, that Vioxx, Celebrex, and Bextra had defects, dangers, and characteristics that were other than what MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS had represented to prescribing doctors, other dispensing entities, the FDA and the consuming public, including the Plaintiff herein.

224. The misrepresentations of MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS were perpetuated directly and/or indirectly by the employees, agents and/or other detail persons of MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS.

225. The misrepresentations of MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS constitute a continuing tort.

226. Through the Vioxx, Celebrex, and Bextra product inserts, advertising, promotional materials, detailing, and aggressive marketing, MERCK, the CELEBREX

DEFENDANTS, and the BEXTRA DEFENDANTS continued to misrepresent the potential risks and benefits associated with Vioxx, Celebrex, and Bextra both before and after Plaintiff's ingestion of the drug.

227. MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS had a post-sale duty to warn Plaintiff, the consuming public, and prescribing physicians about the potential risks and complications associated with Vioxx, Celebrex, and Bextra in a timely manner.

228. MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS misrepresented the safety and efficacy of Vioxx, Celebrex, and Bextra in their labeling, advertising, product inserts, detailing, promotional materials, or other marketing efforts.

229. Plaintiff, Plaintiff's prescribing physician, and other dispensing entities justifiably relied on and/or were induced by the misrepresentations of MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS to Plaintiff's detriment.

230. As a direct and legal result of the negligent misrepresentations of MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS, Plaintiff has suffered serious injuries.

WHEREFORE, Plaintiff demands judgment against MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS for damages, as well as all costs of this action and a trial by jury of all issues to be tried.

**COUNT IV**

**FRAUD (as to all Defendants)**

Plaintiff adopts by reference all of the allegations contained Paragraphs 1 through 206 above, each inclusive, as though fully set forth, pursuant to Rule 1.130 (b), Florida Rules of Civil Procedure.

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231. MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS fraudulently or intentionally misrepresented to Plaintiff and/or Plaintiff's prescribing physician the safety and effectiveness of Vioxx, Celebrex, and Bextra and/or fraudulently or intentionally concealed material information regarding the drugs and/or fraudulently or intentionally misrepresented adverse information regarding the safety and effectiveness of Vioxx, Celebrex, and Bextra.

232. The fraudulent or intentional misrepresentations of MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS were communicated to Plaintiff's prescribing physician with the intent that they reach the Plaintiff.

233. MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS knew that their representations were false.

234. MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS made the fraudulent or intentional misrepresentations and/or actively concealed information about the risks and efficacy of Vioxx, Celebrex, and Bextra with the intention and specific desire that the Plaintiff, the Plaintiff's prescribing physician, dispensing entities and the consuming public would rely on such false information in selecting treatment for pain and inflammation.

235. MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS intentionally concealed material, adverse information regarding the safety and effectiveness of their respective products.

236. MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS made these fraudulent or intentional misrepresentations and actively concealed adverse information at a time when the Defendants knew that Vioxx, Celebrex, and Bextra had defects, dangers, and characteristics that were other than what the Defendants had represented to the prescribing doctors or other dispensing entities, the FDA and the consuming public, including the Plaintiff herein. Specifically, MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS fraudulently or intentionally misrepresented to and/or actively concealed from Plaintiff, Plaintiff's prescribing physician, other dispensing entities, the FDA and the consuming public the following adverse information regarding the Vioxx, Celebrex, and Bextra ingested by the Plaintiff:

- a. Failed to advise Plaintiff, Plaintiff's prescribing physician, and others that Vioxx, Celebrex, and Bextra carried risks of serious adverse effects;
- b. Failed to advise Plaintiff, Plaintiff's prescribing physician, and others that there were serious risks of thrombotic events associated with Vioxx, Celebrex, and Bextra, and, instead, Defendants aggressively marketed, promoted, advertised directly to consumers, and/or sold Vioxx, Celebrex, and Bextra as if there were no risks; and
- c. Failed to advise Plaintiff, Plaintiff's prescribing physician, and others that prior studies, research, reports and/or testing had been conducted linking Vioxx, Celebrex, and Bextra to serious adverse actions.

237. The fraudulent or intentional misrepresentations and/or active concealment by MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS were perpetuated directly and/or indirectly by the Defendant and their employees, agents and/or other detail persons.

238. The fraudulent or intentional misrepresentations and/or concealment by MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS constitute a continuing tort.

239. Through the MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS' product inserts, advertising, detailing, promotional materials, and aggressive marketing efforts, Defendants continued to fraudulently or intentionally misrepresent the potential risks associated with Vioxx, Celebrex, and Bextra.

240. MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS had a post-sale duty to warn Plaintiff, consumers, and prescribing physicians of the risks of Vioxx, Celebrex, and Bextra in their labeling, advertising, product inserts, detailing, promotional materials, and other marketing efforts.

241. MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS fraudulently or intentionally misrepresented the safety and efficacy of Vioxx, Celebrex, and Bextra in their labeling, advertising, product insert, promotional materials, detailing, or other marketing efforts.

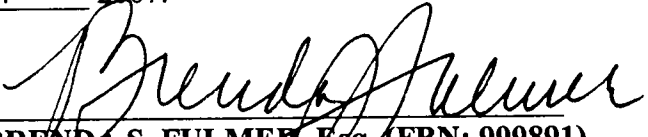
242. Plaintiff, Plaintiff's prescribing physician, and other dispensing entities justifiably relied on and/or were induced by the fraudulent or intentional misrepresentations and/or active concealment by MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS to Plaintiff's detriment.

243. As a direct and legal result of the fraudulent or intentional misrepresentations of and/or active concealment by MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS, Plaintiff suffered serious injuries.

WHEREFORE, Plaintiff demands judgment against MERCK, the CELEBREX DEFENDANTS, and the BEXTRA DEFENDANTS for damages, as well as all costs of this action and a trial by jury of all issues to be tried.

**JURY TRIAL DEMANDED ON ALL ISSUES**

Dated this the 19<sup>th</sup> day of April, 2007. Case 3:07-cv-00897-SDM-AP Document 2 Filed 05/24/2007 Page 58 of 5

  
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